Message

From: Chilakamarri, Varudhini (ENRD) [Varudhini.Chilakamarri@usdoj.gov]
Sent: 12/13/2019 2:49:03 PM
To: Koch, Erin [Koch.Erin@epa.gov]
CC: Oakes, Matthew (ENRD) [Matthew.Oakes@usdoj.gov]; Neumann, Jennifer Scheller (ENRD) [Jennifer.Neumann@usdoj.gov]
Subject: Re: Monsanto amicus consideration - US briefs in Bates and American Cyanamid

Me too.

Sent from my iPhone

On Dec 13, 2019, at 9:46 AM, Koch, Erin <Koch.Erin@epa.gov> wrote:

> Ok by me as well.
>
> **From:** Oakes, Matthew (ENRD) <Matthew.Oakes@usdoj.gov>
> **Sent:** Friday, December 13, 2019 9:44 AM
> **To:** Neumann, Jennifer Scheller (ENRD) <Jennifer.Neumann@usdoj.gov>; Chilakamarri, Varudhini (ENRD) <Varudhini.Chilakamarri@usdoj.gov>
> **Cc:** Koch, Erin <Koch.Erin@epa.gov>
> **Subject:** RE: Monsanto amicus consideration - US briefs in Bates and American Cyanamid
>
> This is OK by me. Thanks Jennifer.
>
> **From:** Neumann, Jennifer Scheller (ENRD) <JNeumann@ENRD.USDOJ.GOV>
> **Sent:** Friday, December 13, 2019 9:42 AM
> **To:** Oakes, Matthew (ENRD) <MOakes@ENRD.USDOJ.GOV>; Chilakamarri, Varudhini (ENRD) <VChilakama@ENRD.USDOJ.GOV>
> **Cc:** Koch, Erin <Koch.Erin@epa.gov>
> **Subject:** RE: Monsanto amicus consideration - US briefs in Bates and American Cyanamid
>
> Minor clarifications to second point below. I have no objections to Erin's edits.
>
> If everyone is OK with this, I would like to run it by Eric Grant.
>
> **From:** Oakes, Matthew (ENRD) <MOakes@ENRD.USDOJ.GOV>
> **Sent:** Friday, December 13, 2019 9:26 AM
> **To:** Chilakamarri, Varudhini (ENRD) <VChilakama@ENRD.USDOJ.GOV>
> **Cc:** Neumann, Jennifer Scheller (ENRD) <JNeumann@ENRD.USDOJ.GOV>; Koch, Erin <Koch.Erin@epa.gov>
> **Subject:** RE: Monsanto amicus consideration - US briefs in Bates and American Cyanamid
>
> I made some minor edits (highlighted below). Use this version if you haven't looked at my prior email yet.
>
> Thanks,
>
> Matt

On Dec 13, 2019, at 9:05 AM, Oakes, Matthew (ENRD) <MOakes@enrd.usdoj.gov> wrote:

Hi Jennifer, Varu and Erin,

Please let me know if you have thoughts/edits/additions to my email below providing feedback on the OSG memo Becca circulated yesterday. Erin – if you would prefer to respond with a separate email that contains more details about the FIFRA program that would also be perfectly appropriate. I'm hoping to get my email back to Becca by noon and can tell her that an EPA email will follow if that's the direction you want to go.

Hi Becca –

Excellent memo. I have a couple of comments.

Ex. 5 AC/AWP/DP

I appreciate your work on this.

Thanks,

Matt

From: Taibleson, Rebecca (OSG) <rtaibleson@jmd.usdoj.gov>
Sent: Thursday, December 12, 2019 2:54 PM
To: Koch, Erin <Koch.Erin@epa.gov>; Oakes, Matthew (ENRD) <MOakes@ENRD.USDOJ.GOV>
Cc: Neumann, Jennifer Scheller (ENRD) <JNeumann@ENRD.USDOJ.GOV>
Subject: RE: Monsanto amicus consideration - US briefs in Bates and American Cyanamid

Matt, Jennifer, and Erin,

Attached here is my draft recommendation memo regarding amicus participation in this case. It is due tomorrow to the Deputy SG. If you are able to review it by late tomorrow morning and send me corrections/edits/thoughts, I would be grateful!

Thanks so much.
Best,
Becca

From: Koch, Erin <Koch.Erin@epa.gov>
Sent: Wednesday, December 11, 2019 4:14 PM
To: Oakes, Matthew (ENRD) <MOakes@ENRD.USDOJ.GOV>; Taibleson, Rebecca (OSG) <rtaibleson@jmd.usdoj.gov>
Cc: Neumann, Jennifer Scheller (ENRD) <JNeumann@ENRD.USDOJ.GOV>
Subject: RE: Monsanto amicus consideration - US briefs in Bates and American Cyanamid

Maybe this will clear things up.... While there is rulemaking authority under FIFRA, most actions taken under FIFRA are informal adjudications to grant or deny pesticide registrations (which are basically licenses in other jargon). The Office of Pesticide Programs also issues regulations (i.e. tolerance rules) under the FFDCA to limit the amount of pesticide residue allowed on food. These two statutes are tied together that in making an affirmative finding under FIFRA for a pesticide registration, EPA's determination must include a determination that human dietary risk from pesticide residues in food is consistent with the safety standard from the FFDCA. See FIFRA 2(bb)(2) (7 USC 136(bb)(2)). So in practice, EPA sets the tolerance through rulemaking to ensure a reasonable certainty of no harm from dietary exposures. For this EPA would do a cancer assessment based on dietary and residential exposures. Then when registering the pesticide product, EPA would approve labeling based on that same safety level. For instance, if an application rate was too high that it would leave residues above the tolerance, it wouldn't be approved.

But cancer risk is also assessed solely under FIFRA for occupational exposures as those are not included in the standard under the FFDCA. Occupational risks are assessed under the FIFRA standard that there be no unreasonable adverse effects to the environment -- defined in 2(bb)(1) as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." For these risks, EPA can weigh risks and benefits to determine whether a pesticide product can be registered. For example, EPA can decide that some higher level of risk to workers is not unreasonable based on the benefit provided.

For glyphosate, EPA determined it is not likely to be carcinogenic to humans. That covers both dietary exposures and occupational exposures, so the difference in the two standards isn't that important here.

Matt – I'm turning to your draft now working on a version with Bob and Amber's comments. I need to leave at 4:45 today. If I can't get through it would you like partial comments tonight or can you wait until tomorrow morning?

Erin

From: Oakes, Matthew (ENRD) <Matthew.Oakes@usdoj.gov>
Sent: Wednesday, December 11, 2019 3:53 PM
To: Taibleson, Rebecca (OSG) <Rebecca.Taibleson2@usdoj.gov>; Koch, Erin <Koch.Erin@epa.gov>
Cc: Neumann, Jennifer Scheller (ENRD) <Jennifer.Neumann@usdoj.gov>
Subject: RE: Monsanto amicus consideration - US briefs in Bates and American Cyanamid

Good question. I've copied Erin Koch, my EPA FIFRA contact, because she knows much more about EPA's FIFRA program than I do. Some of the rulemakings at issue here are FIFRA rulemakings. Glyphosate was registered under FIFRA and the 2017 glyphosate cancer review was done as part of the FIFRA re-registration process. Ex. 5 AC/AWP

Ex. 5 AC/AWP

The product label itself is also approved through formal registration process that imposes a FIFRA labeling requirement. Put another way, EPA reviews and formally approves labels. Those approved labels become FIFRA "labeling requirements." If a registrant wants to change its label it would need to submit a new label to EPA and have that change approved.

The FDA rules largely go to how much of a substance can be included in animal feed or food for human consumption. They are based on the same science, but would not have preemptive effect.

Ex. 5 AC/AWP

Erin – I let us know if you have additional thoughts.

Thanks,

Matt Oakes
Attorney Advisor
United States Department of Justice
Environment and Natural Resources Division
Law and Policy Section
(202) 514-2686

From: Taibleson, Rebecca (OSG) <rtaibleson@jmd.usdoj.gov>
Sent: Wednesday, December 11, 2019 3:22 PM
To: Oakes, Matthew (ENRD) <MOakes@ENRD.USDOJ.GOV>
Cc: Neumann, Jennifer Scheller (ENRD) <JNeumann@ENRD.USDOJ.GOV>
Subject: RE: Monsanto amicus consideration - US briefs in Bates and American Cyanamid

Thanks Matt. Sorry, got pulled onto something else this morning, and am working on this more now!

Ex. 5 AC/AWP

Does EPA or ENRD have a response to that specific issue? I.e., what is the preemptive effect of EPA's glyphosate rulemakings under FIFRA, when those glyphosate rule-makings were not FIFRA regs?

Thanks!
Becca